

CLOTRIMAZOLE- clotrimazole cream
Central Texas Community Health Centers

Clotrimazole Vaginal Cream

Drug Facts

Active ingredients

Clotrimazole 1% (50 mg in each applicatorful)

Clotrimazole 1% (external cream)

Purpose

Vaginal antifungal

Vaginal antifungal

Uses

- treats vaginal yeast infections
- relieves external itching and irritation associated due to a vaginal yeast infection

Warnings

For vaginal use only

Do not use if you have never had a vaginal yeast infection diagnosed by a doctor

Ask a doctor before use if you have

- **vaginal itching and discomfort for the first time**
- **lower abdominal, back or shoulder pain, fever, chills, nausea, vomiting, or foul-smelling vaginal discharge. You may have a more serious condition.**
- vaginal yeast infections often (such as once a month or 3 in 6 months). You could be pregnant, or have a serious underlying medical cause for your symptoms, including diabetes or a weakened immune system.
- been exposed to the human immunodeficiency virus (HIV) that causes AIDS

When using this product

- do not use tampons, douches, spermicides, or other vaginal products. Condoms and diaphragms may be damaged and fail to prevent pregnancy or sexually transmitted diseases (STDs).
- do not have vaginal intercourse
- mild increase in vaginal burning, itching or irritation may occur
- if you do not get complete relief, ask a doctor before using another product

Stop use and ask a doctor if

- **symptoms do not get better in 3 days**
- **symptoms last more than 7 days.**
- **you get a rash or hives, abdominal pain, fever, chills, nausea, vomiting, or a foul smelling vaginal discharge**

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- before using this product, read the enclosed educational brochure for complete directions and information
- adults and children 12 years of age and over:
- **vaginal cream:** insert one applicatorful of cream into the vagina at bedtime for 7 days in a row. Wash applicator after each use.
- **external cream:** use the same tube of cream if you have itching and irritation on the skin outside the vagina.
Squeeze a small amount of cream onto your fingertip. Apply to itchy, irritated skin outside the vagina. Use 2 times daily for up to 7 days as needed.
- children under 12 years of age: ask a doctor

Other Information

- store at room temperature between 2° and 30°C (36° to 86°F)
- see end flaps of carton and tube for lot number and expiration date
- **Tamper-evident: Safety sealed:** the tube opening should be sealed. If seal has been punctured or is not visible, do not use the product.

Inactive ingredients

benzyl alcohol, cetostearyl alcohol, cetyl esters wax, 2-octyldodecanol, polysorbate 60, purified water, sodium phosphate monobasic, sorbitan monostearate

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday- Friday.

Principal Display Panel - 45 gm Tube Label

Austin's Health & Human Services Dept.

Clotrim
VAGINAL
1%45gm
W/APL.

Date:

Name:
Dr.

USE AS DIRECTED.

123456

1/1/01

Clotrimazole VAG.Crm1% 45 gm W/Apl. NDC 76413-326-45

Batch: 123456
Lot: 123456

Exp: 1/1/01
ACTAVIS

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

Austin's Health & Human Services Dept.

Clotrim
VAGINAL
1%45gm
W/APL.

Date:

Name:

Dr.

USE AS DIRECTED.

USAR COMO INDICADO.

123456

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CLOTRIMAZOLE

clotrimazole cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-326(NDC:0472-0220)
Route of Administration	VAGINAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLOTRIMAZOLE (UNII: G07GZ97H65) (CLOTRIMAZOLE - UNII:G07GZ97H65)	CLOTRIMAZOLE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ESTERS WAX (UNII: D072FFP9GU)	
OCTYLDODECANOL (UNII: 461N1O614Y)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	

SODIUM PHOSPHATE, MONOBASIC, MONOHYDRATE (UNII: 593YOG76RN)

SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-326-45	1 in 1 CARTON	08/12/2003	
1		45 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA074165	08/12/2003	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-326) , RELABEL(76413-326)

Revised: 11/2016

Central Texas Community Health Centers